

**Remarks:**

Pending in this application at the time of the November 14, 2005 Office Action were claims 1-49 and 62-73. By this amendment, (1) claims 1, 3-5, 7, 10-12, 14, 16, 17, 19, 20, 25, 28, 30, 32, 33, 35, 37, 43-45, 48, 62, 63, 65, and 69-73 have been amended, (2) claims 24, 26, 31, and 67 have been canceled without prejudice, and (3) claims 74-80 are new. No new matter is added. The currently pending claims are now claims 1-23, 25, 27-30, 32-49, 62-66, and 68-80.

**A. CLAIM OBJECTIONS**

The Office Action objected to claim 19 stating that the second recitation of the phrase "said pharmaceutical seller" was not necessary. Applicant has amended claim 19 eliminating this second recitation. Applicant respectfully submits that this amendment overcomes the objection.

**B. CLAIM REJECTIONS – §112**

The Office Action rejected claim 1 for indefiniteness arising from usage of the term "if" therein. While Applicant contends that claim 1, as originally worded, was not indefinite to persons having ordinary skill in the art, Applicant nevertheless has amended claim 1 to remove the "if" term to expedite allowance of the claim. Applicant notes that the scope of claim 1 has not changed by this amendment to remove "if" therefrom. Applicant respectfully submits that the §112 rejection of claim 1 is no longer applicable.

The Office Action rejected claim 4 as indefinite stating that it was unclear how the claim further defined claim 3 arguing that a computer file is a file that is readable by a computer. The specification, on page 21, lines 17-29, explains that data in reports can be stored in computer files that can have different data formats. The auditing software may not be able to read a report that is stored in a computer file having the data format in which that file was received. Accordingly, for the software to properly read and process the data, some format conversion may be needed. To clarify the operation of this aspect of the invention, Applicant has amended claim 4 (as well as the other claims where this format conversion is

recited) to specify that it is the auditing software that will need to read the computer file. Thus, Applicant respectfully submits that the §112 rejection of claim 4 is no longer applicable.

The Office Action rejected claims 6 and 8 as indefinite for being unclear as to how the content or the determination step is distinct from that recited in claim 1. Applicant notes that these claims involve an auditing process where the audit of a pharmaceutical order is based on two types of audit data (e.g. the first and second associated reports). As an example, the first report can be a retail pharmacy listing and the second report can be a POS or MAR. As explained in the specification at page 16, lines 11-19 and page 22, lines 23-24, this redundancy in audit data can serve to improve the reliability of the audit. Therefore, Applicant respectfully submits that claims 6 and 8 are distinct from claim 1 and are not indefinite to a person having ordinary skill in the art.

Claim 30 was rejected for indefiniteness as being unclear whether the software was embodied and executable on a computer readable medium. Applicant has amended claim 30 to include a processor and recite that the software is executed on the processor. Applicant therefore respectfully submits that the §112 rejection of claim 30 should be withdrawn.

Claim 48 was rejected for indefiniteness because a system claim was dependent on a method claim. Applicant has amended claim 48 to depend on system claim 30, which Applicant respectfully submits has rendered the §112 rejection of claim 48 moot.

Claim 70 was rejected as being indefinite for insufficient antecedent basis for the term "said auditing computer." Applicant has amended claim 70 by removing "auditing" from the claim. Applicant therefore respectfully submits that the §112 rejection of claim 70 should be withdrawn.

The Office Action also rejected claim 69 under §112 paragraph 1, equating the term "computer" as a "means plus function" limitation. Applicant respectfully submits that it is improper to interpret a "computer" as a means plus function limitation. The Office Action's reliance on the Fiers case is misplaced because Fiers does not address the issue of whether it is proper to classify a "computer" as a "means plus function" limitation. Applicant respectfully submits that the term "computer" defines sufficient structure (a processor, memory, etc.) to avoid construction as a "means plus function" limitation. Therefore, Applicant respectfully

submits that claim 69 is not a single element means plus function claim, and the §112 rejection of claim 69 should be withdrawn.

### C. CLAIM REJECTIONS - §103 OBVIOUSNESS

The Office Action rejected claims 1, 9-37, 45-49 and 62-73 for obviousness based on the combination of U.S. Patent 6,003,006 (Colella et. al.) and a publication titled "Pharmaceutical Scam: Use Audit to Detect 'Pyramid Cube Scheme'" (Gardner). The Office Action also rejected claims 2-8 and 38-44 for obviousness in light of Colella and Gardner, and further in view of U.S. Patent 5,890,129 (Spurgeon). Applicant will now explain the shortcomings of the Colella and Gardner references relative to the rejected claims.

#### ***I. The cited references fail to disclose, teach or suggest the use of an "own use" audit to assess pharmaceutical orders where the buyer is a retail pharmacy (or an entity comprising at least one retail pharmacy) that buys pharmaceuticals on behalf of a nursing home.***

Claim 1 recites that the process of performing an "own use" audit on pharmaceutical orders from a buyer, wherein the buyer comprises either a retail pharmacy (or an entity comprising at least one retail pharmacy) that buys pharmaceuticals on behalf of at least one nursing home. The specification at pages 1-4 describe the problems faced by retail pharmacies who attempt to buy "own use" discounted pharmaceuticals on behalf of their nursing home customers.

The Gardner reference cited in the Office Action describes a warning to hospitals to perform audits to assess whether any diversion occurs from their in-house pharmacies. In particular, this Gardner reference provides a warning to hospitals to be wary when "questionable brokers/business enterprises" approach them to buy excess pharmaceuticals in the hospital's pharmacy because sales of such pharmaceuticals to those brokers/business enterprises may violate a variety of laws, including the U.S. statutes affecting "own use" discounts. To combat this problem, the Gardner reference suggests that hospitals should audit their own pharmaceutical usage to determine whether such diversion may be occurring. (See Gardner, page 74).

Gardner addresses tracking pharmaceutical usage within a hospital that has already presumably received an "own-use" discount. Gardner is silent with respect to a process for determining whether an order of pharmaceuticals on behalf of a nursing home but placed by a retail pharmacy (or an entity comprising at least one retail pharmacy) should be deemed eligible for an "own use" discount. In fact, when looking at the pyramid cube scheme shown by Gardner in Figure 1, it can be seen that Gardner differentiates between a hospital's pharmaceutical needs and the pharmaceutical needs of a nursing home by virtue of their positions at opposite corners of the pyramid cube.

Colella fails to bridge the gap left by Gardner because Colella also addresses pharmaceutical distribution in connection with large hospitals and their in-house pharmacies. The Office Action cites col. 3, line 29 through col. 4, line 26 and col. 5, lines 33-43 of Colella for the retail pharmacy-related limitations of the claims, but Applicant notes that Colella fails to address auditing issues faced by *retail* pharmacies (see Application at page 3, lines 20-32). Instead, Colella's invention applies to the in-house pharmacies of large hospitals. While Colella describes how such a large hospital may closely track its pharmaceutical needs to thereby formulate what types of pharmaceutical orders should be placed with a distributor, Colella is silent with respect to auditing methods for determining entitlement to "own use" discounts.

Therefore, when considered in combination with each other, Gardner and Colella fail to disclose, teach or suggest an auditing process that can be used to determine whether a pharmaceutical order from a retail pharmacy (or an entity comprising at least one retail pharmacy) on behalf of a nursing home that needs those pharmaceuticals from the retail pharmacy qualifies for an "own use" discount. Therefore, Applicant respectfully submits that claims 1, 30, 62, and 72 (as well as all claims dependent therefrom) are patentable over the Gardner/Colella combination.

***II. The cited references fail to disclose, teach or suggest the use of two forms of audit data to serve as documentation of a need for "own use"-discounted pharmaceuticals..***

The Gardner reference implies that some form of "documentation" (the specifics of which are left unstated) can be used to review purchase orders for pharmaceuticals to assess

whether an “own use” violations may be occurring at a hospital. (See Gardner, page 74). However, claims 6, 8, and 69 (as well as others) recite that the “own use” auditing process relies upon two different types of audit data. Claim 74 further identifies these types of audit data as retail pharmacy listings and information that summarizes the pharmaceutical needs of a nursing home patient. The Gardner reference is silent with respect to the types of data that can be used together in an “own use” audit, much less the use of two different types of data for such an audit. Furthermore, the Colella reference is silent with respect to “own use” audits and only addresses patient pharmaceutical needs as entered by a nurse through a nurse station or drug dispensing machine. Therefore, Applicant respectfully submits that claims 6, 8, 69, and 74 are not rendered obvious by the combination of Gardner and Colella. For the same reasons, Applicant respectfully submits that claims 13, 15, 16, 33, 36, 40 and 46 (as well as all claims dependent therefrom) are nonobvious in view of the Gardner/Colella combination.

***III. The cited references fail to disclose, teach or suggest adjusting a pharmaceutical order so that its quantity matches the “own use” needs documented by the audit data.***

Claim 28 recites a step of “in response to said comparison resulting in a status determination that said buyer does not qualify for said discount, adjusting said order so that said order is supported by said associated report”. In effect, this amounts to adjusting the pharmaceutical order such that it will match the documented “own use” needs of the buyer. Claims 48, 68, 69, 75, and 76 recite similar limitations. The passages cited in the Office Action from Colella against claim 28 relate to the use of thresholds in connection with inventory tracking and order placement (e.g., “do not place an order for a 100 count bottle of Tylenol until 80 Tylenol pills have been requested”). By contrast and by way of example, the invention of claim 28 relates to re-sizing a given order based on whether the audit data behind that order only in fact supports a lesser amount of pharmaceuticals as qualifying for an “own use” discount. Once again, Applicant notes that Colella is silent with respect to determining eligibility for an “own use” discount. Therefore, Applicant respectfully submits that the limitations of claims 28, 48, 68, 69, 75, and 76 are not rendered obvious by the combination of Gardner with Colella.

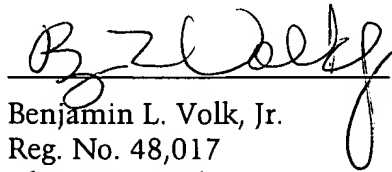
***IV. The cited references fail to disclose, teach or suggest the use of patient identifiers when comparing order data with audit data to assess whether a pharmaceutical order qualifies for an "own use" discount.***

Claim 37 recites that the "own use" audit includes a comparison of the patient identifiers in the order data with the patient identifiers in the audit data, where a sufficient number of matches therebetween are needed to qualify the order for an "own use" discount. Support for this feature is found in the specification at page 19, line 13 through page 20, line 10. The Office Action cites Colella for this feature of the invention, but Applicant notes that Colella, like Gardner, is silent with respect to the use of patient identifiers for auditing purposes, and as such fails to disclose, teach, or suggest the limitations of claim 37. For the same reasons, the Gardner/Colella combination fails to render claims 43 and 44 obvious.

**Conclusion:**

For the foregoing reasons, Applicant respectfully submits that all pending claims of the application are allowable. Applicant has not specifically addressed the Spurgeon reference relative to the arguments herein because the Spurgeon reference is inapplicable to the pertinent claim limitations discussed above in that Spurgeon relates an Internet-based health insurance data exchange system and not to an auditing system for determining whether a pharmaceutical order qualifies for an "own use" discount. Favorable action is respectfully requested.

Respectfully submitted,



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